SUMMARY OF THE ON-SITE ASSESSMENT COMMITTEE MEETING DECEMBER 06, 2001

The On-site Assessment (OSA) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Thursday, December 06, at 9:00 a.m., and 1:30 p.m. Eastern Standard Time (EST) as part of the Seventh NELAC Interim Meeting (NELAC 7i) in Arlington, VA. Its Chairperson, Mr. Alfredo Sotomayor of the Wisconsin Department of Natural Resources, led the meeting. The Action Items are shown in Attachment A. The list of OSA Committee participants is given in Attachment B. The session presentations; "Chapter 3, Appendix C Proposed Changes, the Report of the NELAP Accrediting Authorities' On-Site SOP Subgroup,"Proposed Changes to Chapter 3, Appendix D," and "Impact of PBMS on Laboratory Assessments" are viewable through the NELAC website meeting session link. *The purpose of the meeting was to address items of importance as outlined in the detailed agenda distributed in the conference packets.*

INTRODUCTION

Mr. Sotomayor called the meeting to order by introducing himself as the committee's new Chairperson. He then asked the other committee members to introduce themselves. There was an explanation of the session ground rules given by the facilitator, Ms. Jolinda Summers, of the Anteon Corporation. Mr. Sotomayor reviewed the session agenda.

OSA SESSION TOPICS

Summary of OSA Committee Progress

Mr. Sotomayor reported that Chapter 3, Appendices C and D were presented for discussion at the NELAC-7 Annual Conference held in May 2001 in Salt Lake City, Utah. However, they were not put up for a vote because they needed more work. Since NELAC-7 the OSA committee has been working on: (1) refining Chapter 3, Appendices C and D; (2) reviewing a small number of comments to Chapter 3; and (3) working with an Accrediting Authority Work Group (AAWG) subgroup to improve consistency of laboratory assessments. Mr. Sotomayor indicated that it was the intention of the OSA Committee to incorporate the changes received to date with any modifications suggested from this conference into Chapter 3 and present them for a vote at the NELAC-8 Annual Meeting in July 2002.

Appendix C to Chapter 3

Ms. Mimi Uhlfelder reported that Appendix C was developed to specify the minimum elements to be included in an SOP those accrediting authorities would develop on the process for performing laboratory on-site assessments. Appendix C was originally presented at NELAC-7 for comment and input. Ms. Uhlfelder stated that the draft distributed in the registration packet reflected the comments received at NELAC-7. Also, Ms. Uhlfelder stated that the recommendations from the AA subgroup would be incorporated into Appendix C.

A participant urged that the Appendix be numbered and organized in the same manner as the rest of the chapter.

Ms. Uhlfelder reviewed each section of Appendix C, indicating where revisions had been made.

Introduction

No comments from NELAC-7. No comments at NELAC-7i.

Pre-Assessment

1. Assessment Planning - No comments from NELAC 7. No comments at NELAC-7i.

2. Assessment Team - The last sentence in the handout of this section was separated from the previous one for clarification.

An attendee referred to detection of illegal practices and the process to be used to terminate an assessment at a small laboratory. Mr. Richard Sheibley had concerns about providing too much information on the SOP that could jeopardize an investigation. There would be a risk that laboratories would be alerted and having records destroyed. It was also noted that an abrupt termination would be a "red flag" in and of itself. Mr. Sheibley stated that the AAs must be able to gracefully back out of the assessment. A participant commented that the AAs should avoid language in the SOPs about fraud. He added that the AAs are not looking for fraud, but that if they detect inappropriate practices they continue the assessment and then notify the Office of the Attorney General.

3. Document Review - Comments from NELAC-7 primarily referred to the extent of the document review, the preliminary assessment process vs. the on-site process, and what should be reviewed at each stage. Language was incorporated into this revision to clarify these issues. This section was reordered to include subsections (a) and (b).

Mr. Joe Slayton, Region 3 EPA, requested clarification on the language "initial method validation studies." He felt this may be tied to the proposed PBMS document and he suggested that this matter be tabled until we have the final results of PBMS. Also, Mr. Slayton requested that "Detection Studies" be added to the document review list omitting the word "method."

A participant commented that if Chapter 5 were reorganized it would be useful to highlight the references made in the Appendix to Chapter 5. Ms. Uhlfelder asked participants whether it would be helpful to have this section in a bullet format and to have the Chapter 3 sections referenced. It was determined that those changes would be made in the next version of Appendix C.

Another comment from this session referenced the language, "subcontracting registry." It was questioned whether the intent was (a) to require a 'thing' that is a registry or (b) to require that the auditee be able to readily retrieve records that demonstrate who, when, and if 'something' was subcontracted. Ms. Uhlfelder felt that the latter were, in fact, the intention of the committee. She indicated that the committee would provide clarification in the next version.

A participant offered an editorial comment relating to the end of Section (a): "Other documents required for review should be described in the SOP." He stated that if this is a list of actual documents and records, it should be moved back into the appropriate section. Ms. Uhlfelder agreed that a change in format would be clearer.

4. Accrediting Authority Standardized Assessment Documents and Forms - No comments from NELAC-7.

Mr. Slayton commented on use of the language "standardized NELAC checklists" as a plural. He indicated that there is only one official checklist. Ms. Uhlfelder noted this change.

5. Confidential Business Information - Comments from NELAC-7 recommended that this section be revised to include the applicable State regulations as well as the Federal regulations. Ms. Uhlfelder stated that those changes are reflected in this version.

Mr. Joe Slayton suggested changing the language to read, ". . . applicable State and/or Federal regulations." After deliberation, it was determined that there are State laws that override the Federal law in non-Federal facilities. Questions arose on the stringency between State and Federal laws vs. NELAC Standards. Mr. Sheibley stated that the language needs to be modified and will submit potential language for inclusion.

6. National Security Considerations - No comments from NELAC-7. No comments at NELAC-7i.

Assessment

1. Opening Conference - No comments from NELAC-7. No comments at NELAC-7i.

2. Record Review and Collection - No comments from NELAC-7.

A participant commented that the internal assessments a laboratory is doing of itself, the yearly internal audits that the Quality Assurance Office (QAO) must complete, should be captured. Ms. Uhlfelder replied that this item is covered in subsection (a) under "Document Review" under the "Pre-Assessment" section of this appendix. She also stated that what the OSA Committee intended was to differentiate between those documents that could be reviewed off-site and those that are required to be reviewed on-site for traceability.

3. Assessment Areas - Comments from NELAC-7 concerned procedures for waste management.

A participant indicated that Chapter 5 requires that laboratories maintain an SOP for sample disposal. He requested clarification on whether the OSA SOP of the AAs would prompt assessors to check that a disposal SOP existed or whether assessors would verify compliance with waste management rules. Ms. Uhlfelder stated that the OSA Committee agreed that the existence of the SOP would be verified and that the SOPs content would not be evaluated for compliance with waste management regulations.

4. Staff Interviews - No comments from NELAC-7. No comments at NELAC-7i.

5. Closing Conference - No comments from NELAC-7. No comments at NELAC-7i.

Assessment Reporting

1. Assessment Report - Comments from a NELAC-7 participant had to do with whether there were any specifications for the format of the assessment report.

Ms. Uhlfelder stated that other than indicating that the report had to be in narrative form, and itemizing the areas that the report had to cover, Chapter 3 did not prescribe a specific format for the assessment report. Therefore, Appendix C did not specify a particular format. A participant commented that findings included in the report must include a reference to the applicable section of the Standards. Ms. Uhlfelder indicated that this language was already included in the Appendix.

A participant referred to the language of the second sentence as written. He stated that it appears to make comments and recommendations mandatory for the report and he believed that should be discretionary. Ms. Uhlfelder indicated that this was part of Chapter 3. After discussion, the language of the second sentence referenced was modified to read, ". . . NELAC standard(s), and any comments and recommendations."

2. Roles and Responsibilities - No comments from NELAC-7. No comments at NELAC-7i.

3. Report Release - Ms. Uhlfelder stated that the original draft contained a reference to the National Database and stated that comments from NELAC-7 indicated that this information would not be in the database. Therefore, Ms. Uhlfelder removed this language. This was the only change made to the section.

An attendee questioned whether there should be language included in "Report Release" or "Roles and Responsibilities" sections regarding timelines. He indicated that there are concerns as to when to submit a report, when to expect a corrective action, and related turnaround times. He stated that these items are critical to the smooth functioning of programs especially when dealing with specialty areas, i.e., asbestos testing. Ms. Uhlfelder confirmed that language should be included in the SOP that requires adherence to the timelines or deadlines regarding report release and associated responses.

Assessment Closure

1. Evaluation of the Laboratory's Corrective Action Plan - No comments from NELAC-7.

A participant commented that in the last version of Chapter 6 there was an attempt to separate "evaluation" vs. "assessment." He questioned whether the section title should be modified to change the word from "Evaluation" to "Assessment" as well as in the other sentences of this section to be consistent. Ms. Uhlfelder noted this change.

2. Roles and Responsibilities - Comments received from NELAC-7 referred to changing language so that the SOP would detail the responsibilities of the team and the AA, and to clarifying how the assessment results feed into the accreditation process. Ms. Uhlfelder stated that there were editorial changes made to this section for clarification. No comments at NELAC-7i.

3. Follow-Up Assessments - Comments from NELAC-7 included a request that the OSA Committee give more attention to the minimum requirements of documentation in a follow-up assessment. Ms. Uhlfelder clarified that the committee added that the SOP would need to specify documentation requirements for follow-up assessments but that the Appendix would not specify a list of minimum documents.

A participant asked whether acquiring new instrumentation would constitute a reason for performing a follow-up assessment. Ms. Uhlfelder indicated that an AA would have to decide whether acquiring a new instrument would require an assessment, not necessarily a follow-up assessment.

Mr. Richard Shiebley added that there might be a circular reference in Appendix C. The section on "Pre-Assessment" regarding assessment planning requires describing how the type of assessment is determined. He also stated that there could be an SOP that could be a subset of the general assessment SOP that could describe how to assess for a new method. Mr. Shiebley indicated that there is not a required number of SOPs for on-site assessments and that the necessary information could all be in one or multiple SOPs, as long as all the items in the Appendix are addressed.

After discussion Ms. Uhlfelder concluded that the Appendix requires that the SOP address how to determine the type of the assessment that would be performed. In the case of adding a new equipment or method, she expects that the scope of the possible assessment would be more limited that conducting a complete systems audit.

An attendee suggested changing the language from "minimum documentation" to "minimum document and record review" for better understanding. Ms. Uhlfelder noted the suggestion for change in the next version of the Appendix.

An attendee suggested deleting the sentence dealing with follow-up assessments and stated that "follow-up" really relates to scope. He asked for clarification as to whether follow-up assessments required different documents than ordinary assessments. Mr. Sotomayor indicated that Chapter 3 defines what is a "follow-up assessment". He stated that a follow-up assessment is something that the AA does at its discretion if the AA feels it needs to go back to a laboratory to check that deficiencies have been properly corrected. Mr. Sotomayor stated that some AAs conducted follow-up assessments all the time. The Appendix attempted to communicate that it is important to collect documentation that would give credence to the need for conducting a follow-up assessment.

A participant questioned whether the same assessors that participated in the original assessment would have to take part of the follow-up assessment and if that were the case, whether the assessors would be required to sign additional conflict of interest statements for the follow-up. He wondered whether this could be included as part of the "minimum documentation" in this particular section. Ms. Uhlfelder suggested that adding a "for example" statement in this item might clarify matters.

A participant noted that when a lab is accredited, the accreditation period is for 12 months. If after the initial accreditation, the laboratory wanted to add or delete fields of accreditation, there is no language current written in the Standards covering this and questioned whether some statement should be included regarding this. Ms. Uhlfelder stated that this was discussed at NELAC-7 and included under Appendix C, Pre-Assessment, in the Assessment Planning section.

After further discussion, it was determined that the deciding whether to conduct an assessment when a laboratory wants to add an analyte or a method is the prerogative of the AA and falls under Chapter 4. The AA can grant the accreditations in question by performing a data review, at its discretion. Ms. Uhlfelder stated that perhaps this topic should be taken to the Board of Directors for deliberation. (Section 4.6.2 and Section 3.3.2)

Mr. Dan Hickman commented that Section 3.3.2 only relates to deficiencies and not addition of analytes, methods, or technology because that would not constitute a follow-up assessment. He volunteered to help draft language for Chapter 4 to supply more detail on how adding analytes or methods might trigger an on-

site assessment. Mr. Hickman also stated that there might be a need for a section dealing with conditions for performing additional on-site assessments that are not "follow-up" assessments.

Mr. Joe Slayton, EPA Region 3, indicated that there are reasons other than encountering unethical laboratory practices that might lead to terminating an assessment.

3. Record Retention - No comments from NELAC-7. Mr. Slayton reiterated that he would like to see the language "checklists" changed to "NELAC checklist." Mr. Sheibley commented that "checklists" refer to "all checklists that had been used" and should be part of that method retention policy.

It was suggested by other participants that the language read "any checklist used during the course of the assessment" or simply inserting a parenthesis around the "s" of "checklists" to avoid having to change the standards later when and if other checklists are developed and used. There was no stated resolution to the modified language.

Accrediting Authority Work Group (AAWG) On-Site SOP Subgroup

Mr. Sheibley identified the AAWG members that collaborated on the On-Site SOP Subgroup and gave an overview of the work performed (shown in Attachment D). He commented that the AAWG used the 1999 NELAC Standards, specifically Section 3.5.3, "On-Site Laboratory Records Review and Collection," Section 3.5.4, "NELAC Quality System Checklist," and other areas within Chapter 3 and Chapter 5. It was not the AAWG's goal to add to or change the Standards. The group's goal **was** to look at the existing Standards, come to agreement, and attempt to provide appropriate guidance for the formulation of an on-site SOP for laboratory assessments. Mr. Sheibley stated that the group's work was done independently of the work being done by the OSA Committee on Appendix C, but that there would be some overlap.

A single document will eventually be produced that merges the OSA and AAWG documents as Appendix C of Chapter 3. The AAWG report was circulated to both to the OSA Committee and to the full AAWG and approved by the AAWG as an appropriate approach. Mr. Sheibley clarified that no two on-site assessments could ever be identical and that the mission of the group was to specify the minimum number of laboratory records and data that would be examined during an on-site assessment. As a point of clarification, Mr. Sheibley stated that there were some changes which occurred from the 1999 to the 2000, and then to the 2001 Standards. He stated that the AAWG focused on the 1999 Standards.

Mr. Slayton recommended that the AAWG report include a list of what the workgroup did look at for report preparation, since this was captured in the current report format.

1999 NELAC Section 3.5.3, On-Site Laboratory Records Review and Collection

Mr. Sheibley read some of this Section 3.5.3 language from the 1999 Standards and indicated that **only** the items the AAWG felt needed clarification were covered in the attached report and are listed below:

No comments received from NELAC-7i participants.

e) Mr. Dan Hickman stated that he was not sure if the AAWG had enough foresight to see how these changes are going to apply to the new Standards. As a general comment, he stated that care needs to be taken as to how the changes are folded into the Appendix or the indexing references will be incorrect.

f) Mr. David Friedman remarked that focusing on the consistency on how one conducts an audit is not the goal, but that it should rather be obtaining consistency in laboratory results.

An attendee questioned whether there was a difference in how "must" and "should" were used within this document. Mr. Sheibley responded that when "must" was used, there was a requirement in the Standards that could be tied to that language. If "should" was used, this was a way to get the AA thinking about what needed to be included. Initially, Mr. Sheibley stated, the AAWG disagreed on the distinction, but eventually came to a consensus and all AAs agreed on the scheme. Mr. Slayton recommended developing an "essential" list of steps that "must" be performed.

An AAWG participant amplified the response given by Mr. Sheibley as follows: (1) the "musts" were things that were, in fact, part of the essential items that were required by the Standards and (2) the "shoulds" were the things that the AAs felt were important, not auditable points, but that were necessary to ensure consistency between the AAs and assessors and that they felt were important but not specifically required by the Standards. There is a perception that assessors in different states assess laboratories differently. This language was an attempt to make all assessors look at the same kind of information and approach it from a common understanding.

A participant asked for clarification of Section (f)(2) of the report and how laboratories should handle confidentiality of their clients when the AAs are reviewing data. Mr. Sheibley indicated that if assessors cannot look at the data, they cannot do their job. He also confirmed that the laboratory must know what data the AA would review and take steps to not give away confidential information if that is a concern. Mr. Friedman suggested that having this Appendix specify the types of records that would be reviewed would help

An attendee questioned the language relating to the AA looking at "one batch" and suggested using the language, "at least one batch." Mr. Sheibley indicated that the AAWG had considered this change, but felt that with various States requiring different batch numbers, this again raised concerns about the rigor of assessments among different AAs.

g) A participant stated that spot checks of weights for instrument calibration would be more than ample to ensure that the laboratory quality system is working. He further remarked that having to look at each and every weight is not a good use of an assessor's time. Mr. Sheibley responded that the AAWG did debate on how much verification of this type would be sufficient. It was clarified that the assessor only reviews the certificates and not the weights themselves or the thermometers. Mr. Sheibley made reference to Section 5.9 in the Standards as being essential.

An attendee questioned whether the language of (g) really meant to say that the assessor would look at "all" logs and equipment for initial or ongoing calibration because this would be a significant number of records to review. Mr. Slayton suggested looking only at a minimum number of records or only a percentage.

h) No comments at NELAC-7i.

i) Clarification of the term "origins" was requested by a participant and stated by an AAWG member to be the supplier. A participant stated that she would interpret the origin as what mix the lab started with and not where the vendor got the chemicals to make up that mix. Mr. Sheibley reiterated that the AAWG used the language of the 1999 Standards and it was not the responsibility of the AAWG to modify the Standards. A participant suggested changing the language to read "documentation of origin, purities . . . for traceability." Mr. Sheibley noted this matter for further discussion and debate.

j) No comments at NELAC-7i.

k) No comments at NELAC-7i.

l) A participant questioned whether if an assessor found a problem with a study, there would be an option for the assessor to review another study to verify whether the problem resulted from poor documentation or from other practices. Mr. Sheibley indicated that the second paragraph under (f)(3) of this report addressed this eventuality. It was suggested by a participant that the word "shall" replace "should" in this language to make it credible. The OSA Committee agreed that this paragraph needed some rewording for clarification.

m) It was suggested that the language in this section be used within this document when discussing the number of samples to be reviewed such as in section (f) of this document. Before that can happen, the paragraph must also be reviewed and reworded for clarification.

n) No comments at NELAC-7i.

(p)(q) A participant stated that under the GLP, the laboratory is not required to give assessors any of the content of the internal audits associated with a study. The assessors are not allowed to see that information unless the laboratory volunteers to do this. She stated that this should be made clear prior to the audit that the laboratory had to provide the content information. Full access to the records must be addressed prior to audit. She questioned whether the internal audits are to be sent to the assessor instead of waiting until the on-site visit. Mr. Sheibley responded that the AAWG did not dictate which documents are reviewed at the laboratory or prior to the on-site assessment.

1999 NELAC Section 3.5.4

No comments at NELAC-7i.

Recommendations

Mr. Sheibley reviewed the three recommendations of the AAWG as set forth in Attachment B. He then opened the session up for comments from the participants.

After discussion of the effective date of various versions of the Standards, it was clarified that NELAC assessors should use discretion in enforcing requirements that assessors knew were changed or eliminated in future (but not yet in effect) versions of the Standards. A participant indicated that he was instructed to enforce "only the letter of the 1999 Standards", however, he had to give the laboratories a courtesy notification of any changes of which he was aware.

Mr. Sheibley reiterated that the purpose of Appendices C, D, and the report from the OSA subcommittee, AAWG, is to provide guidance to the AAs who need to develop an on-site SOP to ensure some consistency.

Appendix D to Chapter 3

Mr. Jack Hall reviewed the draft of Assessment Procedures for Test Methods (shown in Attachment C). This version incorporated some of the changes suggested at NELAC-7. He stated that the purpose of this appendix was to provide guidance to the assessors on what to focus on as they review method SOPs and evaluate method performance during assessments.

D.1 Introduction

An attendee wanted more certainty on what and how much would be reviewed for more uniformity. The commenter suggested that language be added to this paragraph requiring listing what documentation was reviewed as part of the assessment.

Mr. Hall stated he had received a suggestion that the word "and" replace the word "or," as follows: "...use is mandated, and to SOPs" in the first sentence of the second paragraph. No further comments were made.

A participant suggested that a reference be made to the language defined in D.3 of this document. Another suggestion was to switch the organization reversing D.2 and D3 for better clarification and to identify Appendix D as Appendix D of Chapter 3.

D.2 Evaluation Phases

Mr. Hall conveyed that there were two alternative approaches shown in the Appendix D.

Alternative 1 - No comments received at NELAC-7i.

Alternative 2 - Mr. Hall stated that he received several comments as to whether to use the word "essential" when referring to performance elements. Based on those comments, he indicated that the word "essential" would be deleted to make it less subjective. Mr. Slayton suggested adding the language, ". . . unless required by program."

An attendee commented that all drinking water methods have to be evaluated individually to comply with the Office of Water endorsement of the NELAC Program. He suggested that a discussion take place with the Office of Water to confirm their position regarding drinking water methods and the three phases noted in D.2. Another attendee suggested that the language be changed to say, "this is the minimum" to avoid rewording the entire paragraph if a specific program required more extensive review.

Assuming acceptance of the Alternative 2 given in D-2, Evaluation Phases, Mr. Hall stated that all SOPs would be reviewed by Phase 1, a, b, and c.

D-2.1.a – An attendee requested changing this item to: "Document all tests performed by a laboratory for which accreditation is sought."

D-2.1.c – An attendee requested changing the language to read, "Are modified or revised in conformance to the laboratory's quality system and applicable regulations, e.g., alternative test procedure approvals." A follow-up comment made by a committee member indicated that this change puts the assessor in the role of having to check regulatory compliance and having to know exactly when this needs to be done. The attendee responded that with drinking water certification, the assessor has this responsibility as a condition of the delegation of the program. He also stated that if modifications to drinking water methods required documented alternate test procedure approvals. Ms. Marlene Moore stated that she has found that some States approve methods without going to the Federal "Alternate Test Procedure" approval process. She also has found that when assessors find significant modifications to instruments that have not been approved by EPA, but are being used for drinking and waste water type analysis, some have been approved, and some have not, but that there are differences between State and Federal approvals. Ms. Moore felt that this is a big issue and needs further discussion for resolution.

D.2.2.a - Mr. Slayton stated that it is important for the assessor to ensure that all equipment will be on-site and functioning for those observations that may take an extensive time to observe. After some discussion, it was requested that further clarification is required. Mr. Sotomayor suggested making the language read that it is the assessor's choice to determine how best to complete that phase.

D.2.2.c - After discussion, it was determined that it is important that test areas be inspected. Mr. Richard Sheibley suggested the following language change to D.2.2:

> *" . . . Methods Manuals by:*
> a. Direct observation of analyst(s) performing test methods or interviewing analyst(s) that perform test methods, and
> b. Inspecting areas and equipment where test methods are performed."

D.2.3 - Mr. Hall explained that the language was meant to reflect that all three steps (a,b,c) are required. An attendee suggested adding an Item (d) to ascertain what analyst worked on a particular sample or batch.

D.3 Essential Performance Elements of Test Methods

Mr. Hall clarified that the Chapter 5 references will be added to this document. Mr. Slayton suggested using the section headers that are used in the Chapter 5, Appendix D sections. After discussion, the following changes were suggested and noted:

D.3.3 - Add expiration dates, and proper storage

D.3.4 - Add acceptance criteria for a calibration

D.3.7 - Add list of qualifiers

Participants recommended that the committee add a section D.4 – "Records" to reflect that the assessor must maintain records of what was reviewed and the review process. The discussion reflected that this should be included in assessor training.

Chapter 5 Checklists

Mr. Charles Dyer led the discussion on this topic. He stated that this is the only official checklist NELAC maintains and requires to be used. Mr. Dyer indicated that the draft of the 2000 Standards checklist is longer than the previous one because now each page stands alone to allow space for assessor comments that can be used at the on-site assessment closing conference. Also, each table now stands alone. Mr. Dyer indicated that examples were set out within parentheses toward the end of the checklist. Mr., Dyer compared the 2000 and 1999 checklists item by item.

The OSA committee will review the new draft and the Accrediting Authorities will review it for clarity and to be sure that the meaning of the Standards was not lost in reformatting the document. The items in the 2000Checklist may not be in the same order as they are in the Standards. Mr. Dyer reorganized the questions to be in more appropriate and logical order. He also indicated he eliminated duplication. A participant requested that a list of changes be distributed to the users. Mr. Dyer agreed that this would be a good tool but that there was no commitment to have this completed by the OSA Committee.

A participant questioned how an assessor would know when a particular checklist becomes official and available for use as opposed to being a draft. Mr. Dyer stated that the final approved checklist would be published on the NELAC Website. The currently approved version, "Chapter 5, Rev. 4G", is posted at this time. The draft version in review at this time is "Chapter 5, Rev 5B". The 1999 versions are Rev. 4 and the 2000 are Rev. 5.

A participant questioned the timeline for releasing the 2000 Checklist. Mr. Dyer stated that laboratories whose current certificates expire on or after June 29, 2002, would be assessed using the 2000 Checklist.
A participant voiced a concern that outdated methods checklists are still posted on the website on the Archive. It was suggested that a caveat be placed on the Archive web page where the checklists are located. Another concern was stated regarding website postings done in WordPerfect and how they are not translated well to those using MS Word. It was recommended that the web postings be done in a format which allows them to be a useful online tool and not post a PDF formatted file.

Chapter 3 Comments

Mr. William Ingersoll announced that no comments suggesting changes were received since NELAC-7 and opened Chapter 3 for discussion by the session participants.

Page 3 of 14 – An attendee suggested that for consistency, the OSA committee should check with Quality Systems Asbestos subcommittee regarding changes to Chapter 5 when referring to the term "bulk."

Appendix A - Ms. Marlene Moore referred to the preparation of an assessment agenda and how this is not a requirement in the Standards. After participant and committee discussion, it was determined that agenda was used in the appendix in its broader, most generic term. The Committee felt that this agenda would be flexible to account for schedules and personnel availability. It was also agreed that the agenda is just a guideline and may or may not be followed as planned.

Effect of Proposed Chapter 5 Revisions to On-Site Assessments

Mr. David Friedman made a presentation regarding the effects that implementing the proposed Chapter 5 changes would bring on conducting assessments. The presentation is shown in Attachment D in its entirety. Mr. Friedman opened the session for comments and they are summarized below.

Participants shared their concerns regarding PBMS and questioned how many NELAC labs and how many regulators receiving NELAC data needed that data to be generated using a specific "approved" method. There was a suggestion of establishing an open assessor forum to voice concerns. A question was then raised as to who would administer this program. Currently, at the local level, it is basically the regulators. It was suggested that an assessor forum would help ensure consistency of assessments. A participant voiced concerns relating to the current system for alternate test procedures, which does not work well. Another participant added that EPA has been unable to turn around methodology in a reasonable amount of time except in the air program. Mr. Friedman clarified that there must be assessor training for how to interpret a method and if there is something missing, it should be added to the proposed approach.

A participant stated his support for Quality Systems PBMS accreditation but felt the need to define for an assessor the steps a lab or analyst must take to establish the scientific validity of a method. He suggested a scientific validation checklist that could be discussed at an assessor open forum.

A participant expressed some concern that what has been presented regarding PBMS was a philosophy but might not be necessarily auditable.

Experiences and Concerns with Laboratory Assessments - Open Session

Mr. Sotomayor requested comments or concerns from attendees on any of their experiences with NELAC laboratory on-site assessments. Discussion ranged from issues directly related to assessments to matters dealing with the interpretation of the standards. Some of these were:

- Announced assessments could be perceived as enforcement actions in some cases when no enforcement was intended. There may need to be more clarity about expectations and responsibilities for unannounced assessments.
- More than one data package must be examined for possible enforcement cases
- Individual items in laboratory assessment reports coming from some AAs do not reflect a "systems" assessment.
- Some assessors conclude that a system is ineffective when they find a single instance of non-conformance.
- Proper assessor training is essential to counteract "creative" interpretations of the standards that do not meet the spirit of a requirement or to allow alternatives that do meet the spirit of a requirement.
- To improve consistency, NELAP needs a viable mechanism for communicating valid interpretations of the standards.
- Assessors should participate in annual or semi-annual conferences.

- A representative set of Quality Manuals and SOPs solicited from various laboratories could be used to evaluate their uniformity and consistency with the standards.
- AAs should encourage assessors to observe and shadow one another.
- The OSA Committee will need to consider how approving Chapter 7 (Field Activities) may require performing a different type of assessment.
- A certain level of consistency has already been achieved in laboratory assessments. This has even affected non-NELAC states in a positive manner.
- An increased insistence on raw data audits has been a positive development.
- Emphasizing systems audits is fine, but this needs to be coupled with performing raw data audits
- It should be possible to combine all initial demonstrations of competency for one analyst into a single form.
- Retrievability of raw data needs to be emphasized more.
- Laboratories with limited QA personnel have found it difficult to accommodate a team of assessors that spend multiple days on-site.
- Assessors need to be flexible to accommodate different eventualities at laboratories. Laboratory systems are established to be functional for laboratories, not assessors.
- As the program matures, assessments may become more efficient and may take less time on-site.
- Assessors and AAs sometimes have scheduling restrictions and laboratories should understand this. Scheduling multiple assessors at a facility is not always easy.
- NELAC assessments take time. It may take a single individual one-day to complete the Chapter 5 QA Checklist. It may take two days to check all analyst-required documentation for a laboratory with 100 analysts.
- Convening an assessor caucus is a good idea.
- Canada has a single laboratory accreditation program; therefore, uniformity is somewhat assured. The second set of assessment conducted by the Canadian program took considerably less time than the first set.
- Once answers to implementation or interpretation concerns are conceived, all affected parties should be notified. An “alert” could be placed on the NELAC Website.
- Laboratories in non-NELAC states can “shop around” for the most “convenient” AA.
- An electronic copy of the standards containing annotations should be created.
- Posting assessment reports without identifying data could help raise and resolve issues of consistency.

Participants determined that further open forums would be valuable to promote communication between laboratories and assessors and to help clarify misinterpretations. It was suggested that perhaps there should be an annual or semi-annual conference or teleconference for the AAs and assessors to discuss issues as well.

"PARKING LOT ISSUES"

The following issues, raised at various times during the session, were recorded for possible discussion in future committee meetings. The issues are grouped around the agenda item that prompted the concern

Appendix C

- Deciding when adding an analyte or method to accreditation scope will require an on-site evaluation. (4.6.2)
- Clarifying mechanics of follow-up assessments. (3.3.2)
- Incorporating or addressing state CBI laws. (3.4.5)
- Accrediting Authority Work Group SOP Report.
- Clarification of the goal or philosophy of assessment SOPs.
- Including records related to internal audits.
- Use of method-specific checklists by assessors.
- Definitions of "batch" throughout the document.
- Clarification on ways of checking calibration certificates for weights, thermometers.
- Clarification of the meaning of the term "origin" in the document.

Appendix D

- Consideration of the alternate test procedure process (ATP) on method evaluation.
- Chapter 5 Checklist
- Providing a summary of checklist changes to laboratories.
- Effect of Chapter 5 Revisions on On-Site Assessments
- Establishing an assessor's forum
- Dealing with "culture" changes.

CONCLUSION

Since the committee's allotted meeting time had expired, Mr. Sotomayor thanked the session participants for their input and adjourned the meeting.

Attachment A

ACTION ITEMS
NELAC-7I CONFERENCE
ON-SITE ASSESSMENT COMMITTEE SESSION
DECEMBER 06,2001

Item No.	Action	Date to be Completed
1.	Decide whether to adopt recommendations of AAWG On-Site SOP Subgroup.	03/02
2.	Incorporate adopted comments and recommendations from AAWG On-Site SOP Subgroup into Appendix C.	06/02
3.	Organize Appendix C using the numbering and format of the rest of the Chapter.	06/02
4.	Incorporate other changes to Appendix C suggested at NELAC 7i.	06/02
5.	Draft new CBI language that considers state rules for inclusion in Appendix C and the body of Chapter 3.	06/02
6.	Reverse the order of sections D.2 and D.3 in Appendix D.	06/02
7.	Contact EPA Office of Water to ascertain position on number of methods that must be reviewed during on-site assessment.	03/02
8.	Clarify responsibility to review methods on site that have been approved under ATP.	03/02
9.	Incorporate other changes to Appendix D suggested at NELAC 7i.	06/02
10.	Consider merging Appendix D with the reformatted Appendix C.	06/02
11.	Complete revisions to Chapter 5 Checklist based on the NELAC 2000 Standards.	03/02
12.	Revise Chapter 5 Checklist based on the NELAC 2001 Standards.	06/02
13.	Monitor Chapter 5 proposed changes for effects they may have on how on-site assessments are performed.	On Going
14.	Continue exploring mechanisms for having assessors exchange information on content, interpretation, and implementation of Standards.	On Going

Attachment B

PARTICIPANTS
NELAC-7I CONFERENCE
ON-SITE ASSESSMENT COMMITTEE SESSION
DECEMBER 06, 2001

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Attachment C

APPENDIX C - Minimum Elements for Accrediting Authority Standard Operating Procedures For On-Site Assessments.

Introduction

Chapter 6 of the NELAC standards defines the process and criteria used by NELAP to determine whether an accrediting authority meets the standards required for recognition. Under this standard (Section 6.2.3.a.1), accrediting authorities are required to maintain documentation about the laboratory accreditation process. Section 6.3.3.1.3.b.8 also states that the accrediting authority's Quality Manual shall include the policies and procedures to implement the accreditation process.

This appendix summarizes the elements to be included by accrediting authorities in SOPs describing on-site assessments of laboratories seeking accreditation under the NELAC standards. At a minimum, the following elements shall be included in the SOPs to ensure consistency of laboratory assessments performed by accrediting authorities.

Pre-Assessment

1. Assessment Planning: The SOP describes how the type of assessment is determined, e.g., initial, renewal, follow-up, etc. Also includes procedures for determining whether the assessment is announced or unannounced, the scope of accreditation (technology, matrix, method, analyte or analyte groups), the estimated time spent on-site, and the assessment team resources needed. The SOP will also address preparation of the on-site assessment agenda.

2. Assessment Team: The SOP describes the qualifications, roles, and responsibilities of the assessment team members, e.g., lead assessor, assessors, and technical support personnel. The SOP shall also include assessment team procedures followed if improper or potentially illegal activities are encountered. The SOP shall detail the circumstances under which the assessment may be terminated including how the assessment team communicates this to the accrediting authority.

3. Document Review:

a. The SOP shall describe how the assessment team will identify and select specific documents and records for review before and during an on-site assessment as required in NELAC Sections 3.4.3, 3.5.3, and 5.12. The SOP shall specify that the document review process includes the following records: the laboratory's accreditation application, previous assessment and PT reports, laboratory organization charts, qualifications statements for all staff involved in the analysis or reporting of results, the laboratory QA manual, SOPs for the fields of testing for which accreditation is sought, laboratory instrumentation and equipment records, standard and reagent preparation documentation, initial method validation studies, Demonstration of Capability test method precision and accuracy records, sample receipt and handling, internal audit records, and the laboratory's annual management review. Other documents required for review should be described

in the SOP: Document control records, corrective action records, complaints records, subcontracting registry, uncertainty calculations (currently needed for WET and Radiochemistry), and an example client report.

b. Findings or observations made during the preliminary document review will be used to determine if the laboratory is ready for an on-site assessment. The accrediting authority may present preliminary findings before the on-site assessment so the laboratory has time to correct them before the assessment team arrival. If the assessment team determines that the laboratory is not ready for an on-site assessment, the SOP shall describe the procedures for laboratory notification.

4. Accrediting Authority Standardized Assessment Documents and Forms: The SOP describes the documents required for the assessment, and which should be assembled prior to the assessment, e.g., Confidentiality Notice, Conflict of Interest Form, Assessor Credentials, Assessment Notification Letter, Attendance Sheets for opening and closing conferences, standardized NELAC checklists, and Assessment Appraisal Forms.

5. Confidential Business Information: The SOP explains the procedures for handling confidential business information in compliance with federal regulations (40 CFR Part 2) and applicable state regulations.

6. National Security Considerations: The SOP describes procedures for handling security requirements at Federally owned or operated facilities.

Assessment

1. Opening Conference: The SOP describes procedures for the opening conference and details the topics to be covered, including the scope of the assessment, the schedule with a tentative time for the exit conference, the NELAC standards used for the assessment, identification of the assessment team, test methods to be examined, records and SOPs required, Confidential Business Information, roles and responsibilities of the laboratory staff, the Assessment Appraisal Form, laboratory questions about the assessment process, and laboratory safety procedures to be followed by the assessment team (lab coats, safety glasses, etc.).

2. Records Review and Collection: In general the assessment team must determine the extent of traceability of standards, personnel training, documents, samples, data, records and problems/resolution (corrective action/follow-up). The SOP describes the procedures to be followed for records review by the assessment team during the on-site visit and the criteria the assessment team will use to determine the accuracy and completeness of the records reviewed or collected during the assessment, e.g., data review
includes tracing samples from receipt to verification of final results, training records review includes a representative sampling from all operational and support areas, etc.

3. Assessment Areas: The SOP describes the areas to be evaluated against NELAC Chapter 5 standards during the assessment, e.g., the laboratory facility, laboratory organization and management, qualifications of laboratory staff, sample handling including receipt and tracking, instrumentation, standards traceability, test methods, data reduction and reporting procedures, and quality control procedures. Additionally, the SOP defines what is objective evidence of conformance to the standard, e.g., records or words or just assessor observation. The SOP also describes the procedures to determine the compliance tools to be used in evaluation of these areas

4. Staff Interviews: The SOP describes the procedures for conducting staff interviews.

5. Closing Conference: The SOP details the procedures to be followed for the closing conference, including the presentation process of deficiencies at the closing conference (written, checklist, verbal), discussion of deficiencies, notification that the assessment team may identify additional deficiencies in the final report, handling disputed findings, when to expect the assessment report, and schedule for renewal and reassessment.

Assessment Reporting

1. Assessment Report: The SOP describes the requirements for the final site report, including the format. The assessment report shall contain the name and address of the audited organization, the date of the assessment, identification and affiliation of the each assessment team member, identification of participants in the assessment, a statement of the objective of the assessment, summary, identification of deficiencies with reference to the specific NELAC standard(s), and comments and recommendations.

2. Roles and Responsibilities: The SOP addresses the roles and responsibilities of the accrediting authority and the assessment team in the report generations, distribution, and release procedures.

3. Report Release: The SOP describes the requirements for release of the assessment report to the laboratory and to the public. The SOP shall address exemptions to the release of proprietary information.

Assessment Closure

1. Evaluation of the Laboratory's Corrective Action Plan: The SOP describes the accrediting authority's procedures for evaluating the laboratory's corrective action plan.

2. Roles and Responsibilities: The SOP details the roles and responsibilities of the assessment team and the accrediting authority in the evaluation of the laboratory's corrective action report in response to the on-site assessment and in the determination of accreditation status.

3. Follow-up Assessments: The SOP describes the circumstances under which a follow-up assessment would be necessary. The SOP also addresses the minimum documentation required for a follow-up assessment.

4. Record Retention: The SOP defines the record retention policy for documentation used in or obtained during an assessment, including assessment reports, checklists, and laboratory responses.

Attachment D

DRAFT

APPENDIX D
ASSESSMENT PROCEDURES FOR TEST METHODS

D.1 Introduction

One function of on-site assessments is to evaluate the capability of a laboratory to perform the test methods for which it seeks or maintains accreditation. Regulatory programs employ various approaches to producing data of known and documented quality including requiring the use of promulgated methods (e.g. Safe Drinking Water Act) or specifying data acceptance criteria in regulations or permits. Chapter 5 of the NELAC Standards requires laboratories to maintain Standard Operating Procedures (SOPs) and Laboratory Methods Manuals, and defines their format.

Assessors review laboratory testing protocols to evaluate conformance to reference methods, when their use is mandated, or to SOPs. By reviewing test methods assessors also verify that a laboratory's quality system and practices ensure that all its analytical activities produce data of known and documented quality.

Appendix D specifies essential performance elements of test methods and the process for evaluating them during assessments. Essential performance elements of test methods are those that directly affect data quality and data defensibility.

D.2 Evaluation Phases

***ALTERNATIVE 1**:* Appendix D requires that assessors evaluate essential performance elements of test methods by completing each of these three phases:

ALTERNATIVE 2: Appendix D requires that assessors evaluate essential performance elements of test methods by completing the three phases specified below for a representative set of test methods and phase one for all test methods used by a laboratory:

1. Review of Laboratory Test Method Documented Procedures

   Assessors must confirm that laboratory SOPs or Methods Manuals:
   a. Document all tests performed by a laboratory.
   b. Include or reference all essential performance elements of test methods.
   c. Are modified or revised in conformance to the laboratory's quality system.

2. Verification of Proper Execution of Test Methods

   Assessors must verify that analysts complete essential performance elements of test methods and determine whether analysts adhere to laboratory SOPs or Methods Manuals by:
   a. Direct observation of analysts performing test methods.
   b. Interviewing analysts that perform test methods.
   c. Inspecting areas where test methods are performed.

3. Audit of Data Generated Using Test Methods

   Assessors must ascertain that:
   a. Results reported are traceable to their raw data.
   b. Results reported can be traced back to calibration data and quality control indicators.
   c. Documents associated with reported results validate or verify the correct execution of a test method.

D.3 Essential Performance Elements of Test Methods

The following outline specifies essential performance elements of test methods. Although these elements apply to a broad range of test methods and analytical disciplines, assessors may at times encounter test methods for which some of these elements are not applicable. This possibility does not constitute an allowance for assuming the inapplicability of an essential element without an informed determination of this claim by a trained assessor.

Attachment D

In all cases, assessors must ensure that the specifications and criteria of essential elements of test methods are in conformance with the NELAC Standards.

1. Test Method Documentation
   a. Written procedure conforming to section 5.10 of the Standards.
   b. Description of all steps necessary to determine the presence, identity, or concentration of an analyte in a sample.
   c. Demonstrations of capability of all analysts or work cells performing the test method conforming to section 5.10.2.1 of the Standards.
2. Laboratory Support Equipment
   a. Availability and use of support equipment (e.g. thermometers, balances, volumetric devices).
   b. Calibration or standardization procedures.
   c. Maintenance procedures.
   d. Corrective actions and contingency procedures undertaken in the event of equipment failure.
3. Reagents and Standards
   a. Availability and use of reagents, standards, and biological media.
   b. Purity of standards, reagents, and biological media.
   c. Verification of identity and concentration of prepared standards.
4. Laboratory Instruments
   a. Availability and use of analytical instruments.
   b. Standardization, tuning, or instrument setup.
   c. Calibration procedures including:
      i. Calibration range.
      ii. Number and concentration of calibration standards.
      iii. Calibration algorithm.
      iv. Reduction of calibration data.
      v. Frequency of calibration checks or of recalibration.
   d. Maintenance procedures.
   e. Corrective actions and contingency procedures undertaken in the event of instrument failure.

5. Sample Preparation and Analysis
   a. Use of sample preparation techniques (e.g. filtration, aliquot selection, digestion, distillation, extraction).
   b. Use of clean-up procedures.
   c. Treatment of interferences before or during analysis.
   d. Arrangement of analysis sequence or run.
6. Quality Control Indicators
   a. Type and frequency of positive and negative controls.
   b. Sensitivity and selectivity of analyses.
   c. Acceptance criteria.
   d. Corrective actions and contingency procedures undertaken when quality control indicators do not meet acceptance criteria.
7. Data Reporting and Documentation
   a. Collection, documentation, and retrieval of raw data.
   b. Raw data media (e.g. hard copy, electronic), storage, and security.
   c. Capacity for reconstructing final results.
   d. Chronology of data reduction operations.
   e. Formulas used to derive quantitative results.
   f. Procedures for confirming or verifying qualitative assessments of reported analytes.
   g. Traceability of data to test methods, analysts, and instruments used to derive them.

   h. Procedures for allowing manual correction of raw data (e.g. manual integration) and for overriding instrument qualitative results.

i. Procedures for data review.

Attachment E

Impact of Proposed Changes to Chapter 5 on Laboratory Assessment Process

DAVID FRIEDMAN
ON-SITE COMMITTEE
DECEMBER 6, 2001

Attachment E

What the changes are not!

- **THE PROPOSED CHAPTER 5 CHANGES ARE NOT PBMS.**
- **PBMS IS A REGULATORY PHILOSOPHY IN WHICH THE REGULATORY AGENCY SETS PERFORMANCE STANDARDS FOR REQUIRED MONITORING RATHER THAN PRESCRIBING HOW THE MONITORING IS TO BE DONE (PROCEDURES TO USE).**
- **THE ISSUE FOR NELAC IS THAT FOR REGULATORY AGENCIES TO BE ABLE TO ADOPT THE PBMS APPROACH THEY NEED CONFIDENCE THAT THE LABORATORIES WILL DELIVER DATA OF KNOWN AND DOCUMENTED QUALITY.**

Attachment E

Regulatory Impact

- **WHILE CHANGE IN THE NELAC STANDARDS ARE NECESSARY FOR EPA AND STATES TO BE ABLE TO IMPLEMENT THE PBMS REGULATORY PHILOSOPHY, IMPLEMENTATION OF THE NELAC STANDARD DOES NOT REQUIRE REGULATORY CHANGES.**

Attachment E

Focus of Proposed Changes

- **FOCUS OF THE CHANGES TO THE STANDARDS IS ON SPECIFYING WHAT THE LABORATORY HAS TO DO TO GENERATE DATA OF KNOWN AND DOCUMENTED QUALITY.**
- **THE GOAL IS TO ASSURE THAT THE LABORATORY CONDUCTS GOOD SCIENCE AND DEMONSTRATES AND DOCUMENTS THE QUALITY OF THEIR DATA.**

Attachment E

Important Change Areas

- **ENSURING APPROPRIATENESS OF PROCEDURES**
- **DOCUMENTING WHAT WAS DONE AND RESULTS**
- **METHOD FLEXIBILITY**
- **QUALITY CONTROL REQUIREMENTS**
- **FOCUS OF ASSESSMENT IS ON MEETING THE NEEDS OF CLIENT (MEASUREMENT QUALITY CHARACTERISTICS)**

Attachment E

Method Appropriateness

- **CHECKING TO SEE THAT METHODS USED WERE VERIFIED AS BEING APPROPRIATE FOR THE TYPE OF SAMPLES BEING ANALYZED.**

Attachment E

Quality Documentation

- **ASSESSMENT FOCUS IS ON CHECKING TO SEE THAT THE QUALITY OF THE ANALYSES HAVE BEEN DOCUMENTED.**
  - **WAS THE QUALITY OF THE DATA CONSISTENTLY DOCUMENTED?**
  - **DID THE DEMONSTRATION EMPLOY APPROPRIATE QC STEPS AND MATERIALS?**

Attachment E

Process Documentation

- **ARE SOPS IN-PLACE FOR ALL WORK?**
- **ARE THEY BEING FOLLOWED?**
- **IS WHAT THE ANALYST(S) HAVE DONE AND THE RESULTS OF THEIR WORK DOCUMENTED?**

Attachment E

Method Flexibility

- **DON'T WORRY ABOUT EPA METHODS AND EPA/STATE APPROVAL PROCESS EXCEPT WHEN CLIENT REQUIRES THAT SPECIFIC METHOD BE USED (ELIMINATES NEED TO WORRY ABOUT WHAT EPA OR STATE REGULATION SAYS).**
- **MAKE CERTAIN THAT WHEN CLIENT REQUIRES THAT A PARTICULAR METHOD BE USED, THAT THE METHOD WAS USED.**
- **DID THE METHOD THAT WAS USED MEET MQC?**

Attachment E

Quality Control

- **WAS APPROPRIATE (TAILORED TO WORK BEING DONE) QUALITY CONTROL PERFORMED?**
  - **SYSTEM CLEAN**
  - **SYSTEM CALIBRATED**
  - **SYSTEM IN CONTROL**

Attachment E

Client Driven Focus

- **BIGGEST CHANGE IS THE ELIMINATION OF THE ONE SIZE FITS ALL APPROACH.**
- **WHAT NEEDS TO BE DONE IS A FUNCTION OF THE PROBLEM OR QUESTION TO BE ANSWERED.**
- **WHEN CONDUCTING AN EVALUATION, ASSESSOR NEEDS TO LOOK AT WHAT WAS THE PROBLEM THAT WAS BEING ADDRESSED.**

Attachment E

Effect on Assessment Process

- **INCREASED EMPHASIS ON LOOKING AT DATA PACKAGES.**
- **DECREASED EMPHASIS ON ADMINISTRATIVE ASPECTS OF THE STANDARDS.**
- **REDUCED EMPHASIS ON ROTE CHECK OFF OF CHECKLIST BOXES AND MORE ON EVALUATING WHETHER WHAT IS BEING DONE IS SCIENTIFICALLY APPROPRIATE.**

Attachment E

Conclusion

- **CHANGE IS THE FOCUS ON GOOD SCIENCE RATHER THAN DOING LABORATORY WORK IN A PRESCRIBED MANNER.**
- **ASSESSOR NEEDS TO FOCUS ON RESULTS AND WHETHER WHAT WAS DONE AND HOW GOOD THE RESULTS ARE HAVE BEEN DOCUMENTED AND WHEN APPROPRIATE.**

Attachment F

Report of the NELAP Accrediting Authorities' On-Site SOP Subgroup
November 19, 2001

Subgroup members: Steve Arms; Dan Hickman; Ken Jackson; Dave Mendenhall; Richard Sheibley

The subgroup met several times by teleconference, between June 18, 2001 and November 15, 2001. A draft report was prepared and circulated for comment, on August 17, 2001, to the NELAP Accrediting Authorities and the NELAC On-Site Assessment Committee. Comments received were considered during ensuing teleconferences and incorporated where appropriate into this final report.

It was agreed that the mission of the subgroup was to provide guidance to better assure uniformity between assessors and between accrediting authorities. While no two on-site assessments can ever be identical, it may be possible to specify a minimum of laboratory records and data that should be examined. The following documents were selected for review:

1. The 1999 NELAC standard Sections 3.5.3 ("On-Site Laboratory Records Review and Collection") and 3.5.4 (Staff Interviews).

2. The NELAC Quality Systems checklist (version dated 2/7/00, and published on the NELAC webpage).

1999 NELAC Section 3.5.3

This Section specifies the minimum record set that must be examined. Only those items that may require quantification are addressed below.

b) previous assessment results and reports including proficiency testing results

Every identified deficiency from the previous on-site assessment must be reviewed and investigated to assure that the agreed corrective action was implemented and remained so.

For every field of proficiency testing, data must be examined from one random event during the previous 2 years (since the last regularly scheduled on-site assessment). The purpose is to verify compliance with Section 2.5; i.e., that samples were handled in the same way as routine samples.

e) quality assurance plan(s) for the laboratory

All items in the Ch. 5 checklist for the quality manual (Section 5.5 of the checklist) must be addressed; either through use of that checklist or its equivalent.

f) standard operating procedures and methodologies for each parameter for which accreditation is sought

The following must be determined for every method SOP:

- completeness (the 23 items in Section 5.10.1.2 of the 1999 standards)
- that it meets the requirements of the mandatory test method
- the QC section of the SOP meets the QC requirements prescribed by the reference method or the QC requirements under NELAC (Section 5.10.1.2.b.12); whichever is more stringent.
- in cases where the laboratory makes allowable modifications to the published method, check that the changes are described clearly in the SOP (see Section 5.10.1.2.b)

While the SOP can refer to the EPA (or SM, ASTM etc.) method, it must provide specific instructions where the published method allows choices. Also, the published method must be available to the analyst, together with the SOP.

For every method, the following must be examined:

1. For every preparation method, all data associated with one preparation batch selected at random. It must be checked that all aspects of the SOP were followed. If the same prep method is used in conjunction with several determinative methods, the prep method need only be examined once.

2. For each determinative method, all data associated with one batch selected at random must be reviewed to determine all aspects of the SOP were followed.

3. For every method, determine that there is a demonstration of capability (initial and on-going). Also, one run should be selected at random, and all raw data associated with that run should be examined. It must be checked that all essential aspects of the SOP were followed (Section 5.10.1.1) and that all QC requirements were met.

   If deficiencies are found, a recurrence could indicate a systematic problem. The assessor should follow an appropriate procedure to determine if this is the case. A systematic problem may be demonstrated by similar deficiencies in other reviewed methods. Otherwise, the assessor should review at least two more record sets from the method to determine if it was just a single occurrence or a systematic problem.

g) maintenance and calibration records of laboratory equipment and instrumentation

All instrument maintenance logs must be examined, and initial and on-going calibration verification must be checked. It must be checked to determine if the laboratory places equipment "out of order" when the equipment is defective or when giving suspect results (Section 5.8.c)

Calibration certificates of every laboratory weight and every NIST-calibrated thermometer must be checked (in accordance with Section 5.9.3). All support equipment must be checked (in accordance with Section 5.9.4.1).

h) procedures for the make-up and calibration of stock solutions and standard reagents

i) origins, purities, assays and expiration dates of primary standards, analytical reagents and standard reference materials

Preparation logs for all standards must be reviewed and compared with the SOP. It should be assured that no prepared standards have exceeded their shelf-life.

At least one key reagent per method must be selected for detailed review of its preparation logs.

j) records associated with method-specific QA/QC requirements

One run should be selected at random, and it should be checked whether the batch was accepted or rejected in conformance with the applicable QC acceptance criteria. Otherwise, this is covered under (f) above.

k) the specific records associated with the initial method validation study in the laboratory which must be examined in detail with the historical calibration data

Covered under (f) above

l) records associated with the methods used to estimate precision and accuracy in general for specific analyses

Covered under (f) above. For every method, where appropriate, it must be checked that detection limits have been determined. One detection limit study should be selected at random, and all raw data associated with that study should be examined.

m) sample receipt and handling documentation

For each report format used by the laboratory, at least one test report must be examined for completeness and conformance with the NELAC standard (Section 5.13).

At least one sample must be traced though the laboratory (including all steps from accessioning through reporting). However, it may be necessary to select more than one sample, the number of samples depending on the structure of the laboratory. A sample must be traced though every analytical section of the laboratory, so that all applicable records listed in Section 5.12.3 of the 1999 standards can be addressed.

If the laboratory has sub-contracted any analytical work, one sample must be selected and traced through the laboratory to assure that sub-contracting requirements have been met. It must be assured that the laboratory has notified its client in advance, and in writing, that sub-contracting will be used and the report has been flagged appropriately.

If the laboratory uses legal chain-of-custody, one sample must be selected and traced through the laboratory, including all steps from accessioning through reporting and disposal, to assure that chain-of-custody requirements have been met (Section 5.12.4).

n) proficiency testing sample receipt and handling procedures

Covered under (b) above.

p) records of any internal audits conducted or corrective actions taken by the laboratory itself
q) documentation of the laboratory's annual and/or ongoing management review

Reports of every internal audit and management review conducted since the previous on-site assessment must be reviewed. Corrective actions resulting from: internal audits; management reviews; complaints; and all proficiency testing failures since the previous on-site assessment must be reviewed.

1999 NELAC Section 3.5.4

For every method, an analyst should be interviewed (subject to staff availability).

NELAC Quality System Checklist

No additional items were identified.

Recommendations

1. The AA Workgroup should recommend the detailed on-site assessment items listed above for incorporation into Chapter 3, Appendix C ("Minimum Elements for Accrediting Authority Standard Operating Procedures For On-Site Assessments.). The AA workgroup should provide specific language for these additions.

2. Pending adoption of the revised standard, the NELAP AAs should agree to voluntarily incorporate these items into their on-site assessment SOPs.

3. Adoption of these recommendations into the standards would require every method SOP to be examined. However, the subgroup believes this will still be a subjective process, compared with the traditional use of method-specific checklists. Consequently, there could be substantial variation between assessors in method review. The NELAC Quality System Checklist addresses all the general QC requirements of the standards, but not method-specific QC requirements where these differ from the general requirements. It should be recommended that the On-Site Assessment Committee develop method-specific QC checklists for those regulatory methods that have differing QC requirements.